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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,798	02/12/2002	Hisao Hiramatsu	10873.872USWO	6236

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EXAMINER

HYUN, PAUL SANG HWA

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,798

Applicant(s)

HIRAMATSU ET AL.

Examiner

Paul S. Hyun

Art Unit

1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 8-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>6/8/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

REMARKS

Claims 1-13 are currently pending. Claims 8-13 have been withdrawn as being drawn to a non-elected invention.

The claim rejection under 35 U.S.C. 112 2nd paragraph cited in the previous Office action has been withdrawn in light of Applicants' arguments. However, all art rejections are maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **1-6** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammer et al. (US 2001/0051377 A1) in view of Kalra et al. (US 5,948,359).

Hammer et al. disclose an automated cartridge-based instrument that conducts measurements. The instrument utilizes a bar-code system to automate the measurement protocols. Each cartridge container that is accommodated by the measuring instrument is assigned a unique bar code adapted to store information regarding the measurement conditions for the particular cartridge. Each cartridge is pre-loaded with samples and reagents (see [0008]) wherein the sample and the reagent are held separately within the cartridge, the sample held in system 76 and the reagent held in reagent pouch 98.

The instrument comprises a bar code reader 200 for reading the bar code attached to each cartridge, and a tracking and control system that conducts the measurement according to the information stored in the bar code (see [0061]). The bar code reader is disposed on cartridge carousel 140, which activates the metering of the contents of the cartridge (see [0010]). The American Heritage Dictionary of the English Language, Fourth Edition defines bar codes as "a series of vertical bars of varying widths, in which each of the digits zero through nine are represented by a different pattern of bars that can be read by a laser scanner." In light of the definition, it appears that specific, non-overlapping identification number is given to each cartridge disclosed in the Hammer et al. reference.

The instrument further comprises a disk inlet 22 that can accept a floppy disk that communicates with a central processing unit (CPU) located in the upper housing cover 14. According to The American Heritage Dictionary of the English Language, Fourth Edition, a floppy disk is "a flexible plastic disk coated with magnetic material and covered by a protective jacket, used primarily by computers to store data magnetically." Hammer et al. disclose that the floppy disk can be inserted into the instrument to provide software updates as well as transport other data and information into and out of the central processing unit (see [0050]). Based on the disclosure, it would have been obvious to one of ordinary skill in the art to use the floppy disk to execute the control program run by the instrument as well as transfer measurement conditions for the cartridges to the hard drive of the CPU.

Although the Hammer et al. reference does not explicitly disclose that the instrument comprises a measurement condition storage means, it is inherent that it comprises a measurement condition storage means that stores the measurement conditions stored in the bar code. If the instrument did not comprise a measurement condition storage means, then the instrument would not be able to make the transition from reading the measurement conditions stored in the bar code to conducting the measurements according to the measurement conditions. Moreover, The Free On-Line Dictionary of Computing defines a CPU as "part of a computer that controls all other parts. The CPU also comprises memory, including RAM, cache, registers and ROM." Based on this definition, it appears that the CPU disclosed by Hammer et al. is capable of storing the measurement conditions.

The instrument disclosed by the Hammer et al. reference differs from the claimed invention in that the Hammer et al. reference does not disclose a means for processing cartridges that lack bar codes.

Kalra et al. disclose an automated apparatus for staining samples disposed on microscope slides. The apparatus utilizes a bar code system to automate the staining procedure for each sample. The apparatus comprises a bar code reader for reading the specific information stored in the bar code assigned to each microscope slide. In the event that a bar-code is not properly read, or is missing, a computer is capable of identifying which slide is "missing" and a menu on the computer screen informs the operator to manually input the missing information or to re-run the scanning procedure (see lines 10-15, col. 17).

In light of the teachings of Kalra et al., it would have been obvious to one of ordinary skill in the art to provide the CPU disclosed by Hammer et al. with a means to accommodate cartridges that lack bar codes such that in the event that a cartridge lacking a bar code is identified, the CPU informs the operator of the apparatus to manually input the missing information or to re-run the scanning procedure so that the automated processing of the cartridges is not interrupted by missing or corrupt bar codes.

In regards to claim 4, although the Hammer et al. reference does not explicitly disclose that the measurement condition storage means stores the measurement conditions for each cartridge in separate areas, CPUs are well-known to be capable of creating separate, easily-identifiable folders for storing specific information corresponding to these folders. It would have been obvious to one of ordinary skill in the art to set up the CPU such that the measurement conditions for each cartridge is stored in a separate folder for organizational purposes.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hammer et al. in view of Kalra et al. as applied to claims 1-6, and further in view of Petersen et al. (US 2001/0012612 A1).

Neither Hammer et al. nor Kalra et al. disclose a waste vessel disposed in the cartridge container to store waste liquid.

Petersen et al. disclose a cartridge adapted to be used for analyzing fluid samples stored therein. The multi-vessel cartridge comprises a chamber 68 that is used to store waste.

It would have been obvious to one of ordinary skill in the art to provide a waste vessel as taught by Petersen et al. to the cartridge disclosed by Hammer et al. so that waste material from the analysis can be separated for easy disposal.

Response to Arguments

Applicants' arguments with respect to the art rejections have been fully considered but they are not persuasive.

Applicants' argument that there is no motivation to combine Hammer et al. with Kalra et al. is not persuasive. The references are analogous in that both references are drawn to automated apparatuses utilizing bar code systems to automate the processing step. The Kalra et al. reference was relied upon for its disclosure of the bar code system. The fact that the apparatus disclosed by Kalra et al. processes microscope slides is not pertinent for purposes of determining whether the Kalra et al. reference can be used as a teaching reference with respect to the Hammer et al. reference. It would have been obvious to one of ordinary skill in the art to apply the advantages of an improved bar code system disclosed by Kalra et al. to the bar code system disclosed by Hammer et al.

Applicants' argument that the combination of Kalra et al. and Hammer et al. does not disclose all the limitations of claim 1 is not persuasive. The fact that the cartridges of the claimed invention intentionally lack bar codes is not patentably distinguishable from cartridges that are missing bar codes. In both cases, what is being claimed is cartridges that do not have bar codes.

The claimed invention comprises two types of cartridges: one type comprising bar codes, and the other type not comprising bar codes. The invention further comprises a means for distinguishing the two types of cartridges and performing different protocols for the two types of cartridges. In the instance that a cartridge comprising a bar code is processed, the invention performs the protocol that is stored in the bar code. In the instance that a cartridge lacking a bar code is processed, the invention instructs the user to input the pertinent protocol. The modified apparatus disclosed by Kalra et al. and Hammer et al. would be analogous to the claimed invention. The modified apparatus would comprise two types of cartridges: cartridges that comprise bar codes and cartridges that lack bar codes. The modified apparatus would also comprise a means for processing cartridges based on the information stored in the bar codes for the cartridges that comprise bar codes, and a means for detecting cartridges that lack bar codes and alerting the user to input the pertinent information for processing the cartridges that lack bar codes.

Applicants' argument with respect to claim 2 is also not persuasive. The Office action dated 5/15/06 indicated that, "The instrument comprises a bar code reader 200 for reading the bar code attached to each cartridge, and a tracking and control system that conducts the measurement according to the information stored in the bar code (see [0061]). **The bar code reader is disposed on cartridge carousel 140, which activates the metering of the contents of the cartridge** (see [0010])" (see page 3 of Office action dated 5/15/06). The carousel 140 was interpreted to be the means for transferring liquid between the vessels of the cartridge container.

With respect to the rejection of claim 7, Examiner thanks Applicants for noticing the omission of the Kalra et al. reference in the rejection. The omitted reference was intended to be included in the rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Devlin et al. (US 2002/0064884 A1).

Devlin et al. disclose an automated analytical instrument that conducts measurements of the contents of the cartridges. The instrument utilizes a bar code system to automate the measurement process.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Art Unit: 1743

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul S. Hyun whose telephone number is (571)-272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

PSH
11/07/06


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